UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL COMPANY LIMITED et al., Plaintiffs, v. NORWICH PHARMACEUTICALS, INC. et al., Defendants.	**Civil Action No. 20-8966 (SRC)** **OPINION & ORDER**

CHESLER, District Judge

This matter comes before the Court on two motions: 1) the motion to exclude certain opinions of Defendant's expert Dr. Zaworotko, pursuant to Federal Rule of Evidence 702, by Plaintiffs Takeda Pharmaceutical Company Limited and Takeda Pharmaceuticals U.S.A. Inc. (collectively, "Takeda"); and 2) Takeda's motion for summary judgment, pursuant to Federal Rule of Civil Procedure 56, that seven claims are infringed and not invalid. Defendant Norwich Pharmaceuticals, Inc. ("Norwich") has opposed both motions. For the reasons that follow, the motion to exclude will be granted in part, and the motion for summary judgment will be denied.

I. The motion to exclude certain opinions of Defendant's expert Dr. Zaworotko

Takeda contends that Dr. Zaworotko is an expert in crystallography and crystal engineering, but is not qualified to testify about whether something constitutes a sale, within the meaning of 35 U.S.C. § 102(a)(1). Takeda asks that Dr. Zaworotko be precluded from opining on questions of whether something was sold or offered for sale.

In response, Norwich declares that Dr. Zaworotko will not offer any opinions on questions of whether something was sold or offered for sale. Norwich offers this explanation of

how Dr. Zaworotko's specialized knowledge will help the trier of fact to understand the evidence:

> Norwich's expert, Dr. Zaworotko, has developed opinions about the material that is the subject of these "on-sale bar" documents. Specifically, he offers opinions within the scope of his expertise as a crystallographer / crystal engineer that various lots of lisdexamphetamine dimesylate drug substances and drug products referenced in the "on-sale bar" documents (1) were crystalline in nature, (2) had an XRPD pattern that meets the limitation recited in claim 2 of the '253 patent, (3) would have unit-cell parameters that meet the requirements of claim 7 of the '253 patent, and (4) were incorporated into a drug product with at least one additive and a certain level of chemical purity. These opinions all relate to various limitations in the asserted claims (claims 2, 7, and 12) of the '253 patent, and they are squarely within Dr. Zaworotko's technical expertise.
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> Dr. Zaworotko also would opine that, if the Court separately concludes that the lisdexamphetamine dimesylate at issue was the subject of a sale or commercial offer for sale prior to June 2, 2008, then the asserted claims of the '253 patent are invalid because the material meets all of the limitations of the asserted claims. Other than the "sale/commercial offer for sale" issue, that opinion again is squarely within the realm of a technical expert.

(Def.'s Opp. Br. at 1-2.) Norwich thus seeks the admission of opinions that fall into two categories: 1) opinions based on his expertise as a crystallographer that certain evidence reflects certain limitations in the asserted claims; and 2) ultimate conclusions of patent invalidity contingent on this Court's future determination that a sale occurred.

As to the second category, Norwich has failed to persuade the Court that the expert's opinions about patent invalidity are admissible under Rule 702. "[A]n expert witness is prohibited from rendering a legal opinion." Berckeley Inv. Grp., Ltd. v. Colkitt, 455 F.3d 195, 217 (3d Cir. 2006); M.S. v. Susquehanna Twp. Sch. Dist., 969 F.3d 120, 129 (3d Cir. 2020) (citing Berckeley). Moreover, testimony in which Dr. Zaworotko speculates about this Court's future determinations, and offers contingent legal conclusions based on speculative scenarios, are

not a use of specialized knowledge that will help the trier of fact to understand the evidence, as required by Rule 702(a). All opinions in this second category are inadmissible.

As to the first category of opinions, such opinions appear to make use of special knowledge to help the Court understand certain evidence, without offering impermissible legal conclusions. In reply, Takeda argues that "Norwich has not satisfied its burden of demonstrating which of Dr. Zaworotko's opinions concerning the on-sale bar are admissible." (Pls.' Reply Br. at 1.) Nonetheless, Takeda's Reply Brief does not end up asking for the exclusion of all of Dr. Zaworotko's opinions:

> Takeda respectfully requests the Court exclude all of Dr. Zaworotko's on-sale bar opinions except for those analyzing the technical aspects of the AMRI Report and Quality Operations / Operations Report that were identified by Norwich as "requir[ing] expert assistance."

(Pls.' Reply Br. at 6.)

The Court has reviewed Dr. Zaworotko's opening expert report and finds that there appears to be substantial overlap between the subject matter that Takeda allows is admissible (the opinions about the AMRI Report and Quality Operations/Operations Report) and the subject matter in the first category that Norwich describes as "squarely within Dr. Zaworotko's technical expertise." (Def.'s Opp. Br. at 1.) Dr. Zaworotko's report identifies the AMRI Report as an XRPD analysis prepared by AMRI for lots 04060014 and 04060026, and offers opinions about inferences that may be made about characteristics of those lots that embody limitations in claims 2 and 7 in the '253 patent. (Zaworotko Opening Report at ¶¶ 174, 175, 179-184.) Dr. Zaworotko's report identifies the Quality Operations/Operations Report as prepared by Patheon on capsules it produced from materials which included lot 04060014. (Id. at ¶¶ 177, 178, 185.) Dr. Zaworotko's report offers opinions about inferences that may be made about characteristics

of those capsules that embody limitations in claim 12 of the '253 patent. (Id. at ⁋⁋ 186-190.) These opinions, which apply Dr. Zaworotko's expertise in crystallography to the information contained in the AMRI Report and Quality Operations/Operations Report, and which result in inferences about embodiments of asserted claims in the '253 patent, in regard to those reports, are admissible under F.R.E. § 702(a). As to these opinions, Norwich has satisfied its burden of demonstrating admissibility. As to the remainder of Dr. Zaworotko's Opening Report, Norwich has not demonstrated that the opinions are admissible, and those opinions are not admissible and will be excluded.

II. The motion for summary judgment of infringement and no invalidity

Plaintiffs move for summary judgment that claims 1 and 4 of U.S. Patent No. 7,655,630 ("the '630 patent"), claim 2 of U.S. Patent No. 7,662,787 ("the '787 patent"), claim 14 of U.S. Patent No. 7,687,466 ("the '466 patent"), claim 4 of U.S. Patent No. 7,105,486 ("the '486 patent"), claim 5 of U.S. Patent No. 7,678,770, and claim 7 of U.S. Patent No. 7,671,031 (collectively, "the Asserted Claims"), are infringed and not invalid. Defendant opposes the motion.

Takeda's moving brief first addresses the issues of invalidity due to obviousness, and then the issues of invalidity under 35 U.S.C. § 112. As to obviousness, in brief, Takeda makes several arguments: 1) the Asserted Claims are not obvious over Norwich's primary prior art references: the PDR, Patrick, Miller, and Engel; 2) the "prior art references do not disclose the claimed lisdexamfetamine, any properties thereof, dimesylate salts, or predictable solutions for obtaining abuse-resistant amphetamine derivative prodrugs" (Pls.' Br. at 8); 3) "isolated L-lysine-d-amphetamine is not obvious in view of Norwich's prior art references" (Pls.' Br. at 12);

4) "the dimesylate salt of lisdexamfetamine is not obvious in view of Norwich's prior art references" (Pls.' Br. at 17); 5) "Norwich has failed to offer the requisite proofs for a reasonable expectation of success of either the claimed isolated lisdexamphetamine or its dimesylate salt" (Pls.' Br. at 22); and 6) "Norwich offers no evidence that the water content limitation in claim 14 of the '466 patent would have been obvious" (Pls.' Br. at 22). In opposition to all of these points, Norwich contends that factual disputes preclude the entry of judgment as a matter of law, and that this is a "classic battle-of-the-experts." (Def.'s Opp. Br. at 2.) This Court agrees with Defendants that the obviousness dispute presents a classic battle between competing experts.

The Federal Circuit has set forth these fundamental principles to guide decision on a motion for summary judgment on an issue of obviousness:

> Obviousness is a question of law that is reviewed de novo, based on underlying factual questions that are reviewed for clear error following a bench trial. The underlying factual inquiries include: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of non-obviousness. Summary judgment of obviousness is appropriate if the content of the prior art, the scope of the patent claim, and the level of ordinary skill in the art are not in material dispute, and the obviousness of the claim is apparent in light of these factors.

MRC Innovations, Inc. v. Hunter Mfg., LLP, 747 F.3d 1326, 1331 (Fed. Cir. 2014) (citations omitted). In this case, the content of the prior art is much disputed and the subject of detailed opinions of numerous experts, as are the questions of what the prior art references would have suggested to the skilled artisan and whether there is a basis to find that the skilled artisan would have had a reasonable expectation of success in pursuing certain options. As Plaintiff's brief itself shows in Appendix A, Defendants have assembled a team of experts to opine on multiple

theories of obviousness for every claim at issue. Summary judgment of obviousness is not appropriate.

As to the issues of invalidity under 35 U.S.C. § 112, Takeda argues that Norwich's case is fatally flawed by a key legal error: their experts erroneously analyzed versions of patent specifications that were not the latest filing. Takeda has not, however, developed this argument sufficiently to allow this Court to evaluate it at this juncture. Before this Court can consider the question of whether this is a fatal legal error, it must ascertain what the difference is between the versions, and determine whether the difference is material to the 35 U.S.C. § 112 inquiry. Takeda's brief neither identifies the differences between the versions nor explains why any differences are material. As a result, this Court cannot determine whether any potential error is harmless. Takeda has failed to persuade the Court that it is entitled to judgment as a matter of law as to the issues of invalidity under § 112.

As to infringement of the Asserted Claims, Takeda contends that it is entitled to judgment of infringement as a matter of law because Norwich has stipulated to infringement. Takeda points to two documents on the case docket, the Stipulation and Order entered by Magistrate Judge Waldor on July 21, 2022 (Docket Entry No. 330), and the Stipulation and Order entered by Magistrate Judge Waldor on August 31, 2022 (Docket Entry No. 363). In these documents, the parties agreed to a set of stipulations which generally follow this form:

> Norwich agrees that the submission of ANDA No. 214547 infringed and the commercial manufacture, use, sale, or offer for sale within the United States, and importation into the United States of Norwich's ANDA Products presently described in ANDA No. 214547 before the expiration of the '735 patent would infringe claim 15 of the '735 patent, if valid and enforceable.

(Stipulation and Order of July 21, 2022 at 2.) Every stipulation of infringement contains the contingency, "if valid and enforceable." These contingency provisions contain unambiguous language that expresses that a determination of validity and enforceability is a condition precedent to that stipulation of infringement. ***If*** and when this Court determines that a claim at issue is valid and enforceable, then the stipulation of infringement becomes effective. At this point, those stipulations are contingent on future events. As to infringement, the motion for summary judgment will be denied.

For these reasons,

IT IS on this 13th day of October, 2022

ORDERED that Takeda's motion to preclude (Docket Entry No. 371) is **GRANTED** in part and **DENIED** in part; and it is further

ORDERED that Takeda's motion to preclude is **GRANTED** to the extent that Dr. Zaworotko's expert opinions are excluded except for those analyzing the technical aspects of the AMRI Report and Quality Operations/Operations Report, as described above; and it is further

ORDERED that Takeda's motion for summary judgment (Docket Entry No. 373) is **DENIED**.

s/ Stanley R. Chesler
STANLEY R. CHESLER
United States District Judge